West v. Smith

United States District Court for the District of Vermont

Case No. 02:19-cv-00081-WKS

Declaration of Kevin Costello

June 11, 2021

Exhibit 2

VitalCore Health Strategies Redefining healthcare	**Form: PR-7.0**
SITE-SPECIFIC POLICY and PROCEDURE ADDENDUM	

Health Services Policy and Procedure	**Title: Hepatitis C Virus Treatment Program**	VitalCore Health Strategies Redefining healthcare
	#: B-IC-01.06	
	Page 1 of 4	

Approved by:	Original Date Issued:	1-1-2021
Kathleen F. Maurer, MD Kathleen F. Maurer, MD (Dec 31, 2020 12:50 EST) Kathleen Maurer, MD, Regional Medical Director	Replaces Version Issued:	N/A
	CURRENT VERSION EFFECTIVE:	1-1-2021

Vermont Department of Corrections Policy:

Vermont Department of Corrections – VitalCore Regional Office will follow VitalCore Policy (B-01.00 Infection Prevention and Control Program).

REFERENCES:
NCCHC: Standards for Health Services in Prisons, 2018, P-B-02
ACA: Performance Based Expected Practices for Adult Correctional Institutions-5th Ed., 2018; 5-6A-4354
VitalCore Infection Prevention and Control Manual
The Infectious Diseases Society of America (IDSA)
American Association for the Study of Liver Diseases (AASLD) (www.HCV Guidelines.org, updated 8/27/2020).

Procedure:

As of January 1, 2021, there are 115 known patients with chronic hepatitis C viral (HCV) infection in VT DOC facilities.

Treatment Objectives
The Hepatitis C Virus (HCV) treatment program is designed to meet the following key objectives:

1. All patients entering the VT DOC system are screened on admission for HCV utilizing the concept of "opt out" screening. This practice has been standard in the system for several years and gives confidence that the HCV status of the population is known. Positive antibody tests automatically reflex to PCR testing. If the PCR testing is positive, the diagnosis is confirmed. Turnaround time for these two tests is approximately 2 to 3 weeks. If negative, the test is repeated in 6 months.
2. All patients with chronic HCV who currently occupy the Vermont DOC system will be treated as soon as possible if the course of treatment can be completed during confinement including the required SVR testing to confirm Sustained Viral Response (SVR). This period is 4 - 6 months. Especially compromised patients, those with decompensated cirrhosis even with short term

stays will be referred immediately to UVMMC or Dartmouth-Hitchcock Medical Center for assessment and care. If necessary, follow-up care can continue after patient release.

3. There are three separate cohorts defined by sentence status or non-sentence status of HCV patients in the VT DOC system. Further, patients with HCV disease without cirrhosis will be treated by prescribers within the Vermont DOC system. Those with cirrhosis, whether compensated or decompensated will be referred for treatment to an academic medical center (UVMMC, Dartmouth-Hitchcock Medical Center) for care.
4. Patients entering the VT DOC system on Direct Acting Anti-viral therapies for chronic HCV infection will be maintained on treatment unless there is a clinical indication to discontinue.

Three Categories of Patients based on Incarceration/Detainment Classification

Category 1. Remaining sentence length greater than 4 - 6 months.

Patients with known remaining sentence lengths that are greater than 4 - 6 months will have treatment initiated as soon as possible. Those with the least remaining sentence length will be treated first.

Category 2. Remaining sentence lengths indeterminant.

This is a complex population as the patient release date is unclear. This group includes patients with remaining sentence lengths that are indeterminant (the minimum date is past, but there is at least 4 - 6 months remaining to reach the maximum, and specific date of release is unknown) will be individually evaluated to estimate the most likely remaining period of incarceration. This estimation will be made with assistance from the VT DOC classification personnel and case managers who may be familiar with the likely dates of release. Patients deemed to have an estimated sentence length of 4 – 6 months or longer based on the assessment of VT DOC classification personnel and case managers will be evaluated for treatment of HCV infection.

Category 3. Pre-trial detainee population.

This is the most complex of the three population groups. Pre-trial detainee populations have unpredictable lengths of stay due to bond or bail outs, court determinations, and other unscheduled interventions. Many detainees cycle in and out of the VT DOC multiple times a year. Initiating and potentially interrupting Direct Acting Antiviral (DAA) therapies for this patient population could lead to treatment failures and/or drug resistance limiting future treatment options. The focus for this patient population will be screening, education, and referrals for follow-up care. All pre-trial detainee populations will be provided "opt-out" screening for chronic HCV infection. Patients with confirmed infections will receive patient education on reducing transmission to others and a referral for treatment in the community. Many of these patients have concurrent opioid use disorders and will receive follow-up care upon release at a community treatment center or either a HUB or Spoke in the Vermont MAT system. A pilot to provide DAA therapies for chronic HCV infection at these sites is being pursued to strategically consolidate and simplify care for these patients.

Treatment Protocols

The Vermont DOC patients will be treated using the simplified protocols published by The Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) (www.HCVGuidelines.org, updated 8/27/2020). These guidelines are updated regularly and are readily available at www.hcvguidelines.org. These guidelines include specific treatment protocols for patients with no cirrhosis, with compensated cirrhosis, and with decompensated cirrhosis. The key elements of the protocol for the patients of VT DOC are included in the following proposed treatment plan.

Proposed Hepatitis C Treatment Plan:

1. ***Patients will be considered for treatment who are sentenced and will be in the custody of the Department of Corrections for a minimum of four to six months duration which will allow time for workup and treatment, and confirmation of cure.***
2. ***VitalCore Health Strategies will utilize the simplified HCV Treatment Algorithm approved by AASLD/IDSA for all patients sentenced to the Vermont Department of Correction.***
3. ***Patients with chronic HCV infection with a Fib-4 <3.25 and no clinical evidence of cirrhosis will be treated with Mavyret for 8 weeks unless contraindicated, at which time Epclusa would be considered.***
4. ***Patients with FIB-4 >3.25 or clinical evidence of cirrhosis or other complicating medical conditions will be referred to UVMMC or Dartmouth-Hitchcock Medical Center, for additional assessment and treatment recommendations as indicated.***

In the VT DOC system, patients with chronic HCV separate into two groups: those without cirrhosis and those with cirrhosis. Those without cirrhosis will be treated in house by VitalCore Health Strategies prescribers. Those with cirrhosis, whether compensated or decompensated, will be referred to an academic medical center for treatment (UVMMC or Dartmouth-Hitchcock Medical Center).

Treatment Group 1. Patients with chronic HCV and who have no evidence of liver cirrhosis and have not been previously treated for HCV.
This cohort is identified by those patients with the FIB-4 calculation less than 3.25. These patients are assessed with a comprehensive medical evaluation described in the attached protocol. The treatment of this group utilizes either Mavyret or Epclusa, both of which are pangenotypic (treat all HCV genotypes) direct acting antiviral medications. This is the simplified protocol that applies to patients without cirrhosis. Patients who qualify for this protocol will be treated by in house prescribers at the Vermont DOC. In more detail, patients who do not qualify for this treatment protocol include the following:

Who Is *NOT* Eligible for Simplified Treatment
Patients who have any of the following characteristics:
Prior hepatitis C treatment
Cirrhosis (see simplified treatment for treatment-naive adults with compensated cirrhosis)
HIV or HBsAg positive
Current pregnancy
Known or suspected hepatocellular carcinoma
Prior liver transplantation

*From www.HCVGuidelines.org, downloaded 11.09.20. Updated 8-27-2020.

Treatment Group 2. Patients with chronic HCV and who have liver cirrhosis, both compensated and decompensated, and patients who are not eligible for simplified treatment due to certain medical conditions as noted above. This patient cohort is clinically complex and will therefore be referred to an

academic medical center for evaluation and treatment as recommended. Care from academic medicine specialists will be provided in-person and via tele video-consultations if available.

Medication for Opioid Use Disorder (MOUD) Treatment. All patients with HCV will be assessed for substance use disorder and if an opioid use disorder is diagnosed, will be assessed for medication assisted treatment (MAT) and will be offered MAT if medically appropriate and the patient prefers this care. Patients who enter the system on MAT will be continued on that care.

Follow up care for those patients with cirrhosis. All cirrhotic patients will be scheduled for follow-up liver ultrasound every six months to assess for hepatocellular carcinoma.
This is the link to the hcvguidelines.org website.
https://www.hcvguidelines.org/treatment-naive/simplified-treatment
This is the treatment protocol for patients with chronic HCV without hepatic cirrhosis.

AASLD-IDSA_HCV-Guidance_TxN-Simplified

B-IC-01.06 HEP C- VT DOC.12.31.2020

Final Audit Report 2020-12-31

Created:	2020-12-31
By:	Lorelei Ammons (lAmmons@vitalcorehs.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAhv2lZAGalLLcugSa_J1jAqotboGqq0QB

"B-IC-01.06 HEP C- VT DOC.12.31.2020" History

Document created by Lorelei Ammons (lAmmons@vitalcorehs.com)
2020-12-31 - 5:43:43 PM GMT- IP address: 67.174.113.1

Document emailed to Kathleen F. Maurer, MD (kmaurer@vitalcorehs.com) for signature
2020-12-31 - 5:44:43 PM GMT

Email viewed by Kathleen F. Maurer, MD (kmaurer@vitalcorehs.com)
2020-12-31 - 5:48:31 PM GMT- IP address: 104.47.57.254

Document e-signed by Kathleen F. Maurer, MD (kmaurer@vitalcorehs.com)
Signature Date: 2020-12-31 - 5:50:42 PM GMT - Time Source: server- IP address: 73.234.132.25

Agreement completed.
2020-12-31 - 5:50:42 PM GMT